

10. (Amended) A The system as defined in claim 9, wherein said first composition ~~comprises a powder and wherein said urea~~ has a mean particle size of less than about 0.1 mm.
11. (Amended) A The system as defined in claim 10, wherein said second composition further comprises agar and a pH adjuster.
12. (Amended) A The system as defined in claim 9, wherein said indicator comprises phenol red.
13. (Amended) A The system as defined in claim 9, wherein said indicator comprises a pH indicator that changes color when the pH of said second composition is increased above a certain level.
14. (Amended) A The system as defined in claim 9, further comprising a film top covering said first well and said second well of said container, ~~said top comprising a film, said film being water impermeable over said first well.~~
15. (Amended) A system for detecting the presence of urease comprising:
a container including a well;
a composition contained in said well, said composition comprising a fine powdered urea and a ~~dry~~ fine powdered indicator, said urea being capable of being converted into ammonia when contacted with urease and said indicator being configured to indicate the presence of ammonia.
16. (Amended) A The system as defined in claim 15, wherein said urea ~~comprises a powder~~ having has a mean particle size of less than 0.1 mm.
17. (Amended) A The system as defined in claim 15, wherein said composition further comprises ~~an~~ a fine powdered anti-caking agent.
18. (Amended) A The system as defined in claim 15, wherein said indicator comprises a pH indicator that changes color when the pH of said composition is increased above a certain level.

REMARKS

Favorable reconsideration of this application as presently amended is respectfully requested. Claims 1-18 are pending. No new matter is added.

35 U.S.C. §102 Rejection

Claims 1, 5-7, 15-16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0369292 A1 to Rothgang et al.

The Rothgang patent teaches the use of a urea that has been stored dry to prevent hydrolysis prior to activation through the use of a liquid. At page 5, lines 7 - 9 of the English translation, Rothgang teaches the use of a dry, compressed reagent mixture, such as a tablet, as

the preferred configuration. Rothgang goes on to say that they (reagent mixture) can be placed, as a powder, in capsules or other "water soluble or easily destroyed material." (Page 5, lines 9-12) When using the compressed reagent mixture, the specimen is first deposited on the reagent mixture and water is added to the mixture to initiate the reaction process. (Page 5, lines 17 – 18; lines 24 – 25 – page 6, lines 1 – 7) When using the powder contained within a container, the water is added to the biopsate and either mixed with the ingredients of the container or the container is dissolved or crushed within the water. (Page 5, lines 24-25 – Page 6, lines 1-5)

While Rothgang discloses "they may also have been filled as a powder mixture in appropriate capsules of hardened gelatine or another water-soluble or easily destroyed material" the use of any of the components a finely powdered form, such that the moisture in the sample can adhere the fine powder to the sample, is not disclosed or suggested by Rothgang. Rothgang's disclosure of the product being "compressed....in a pressed form, usually a tablet" teaches away from the importance of the first composition being in a form that can be adhered to the sample by the moisture in the sample.

As stated in the specification at page 7, lines 13-17, as the moisture inherent in the sample causes the powdered urea to adhere, the sample is able to be coated, or floured, with the urea composition thereby covering the sample with urea. The reaction starts because the urea is destroyed by any bacteria in the sample. The sample is then placed into the indicator composition where any urease reacts with the urea to change the pH and turn the coated sample the appropriate indicator color. The "floured" sample is very hygroscopic and pulls water and indicator into the biopsy surface after being placed in the gel. Under Rothgang teachings the urea would not be in a form that could coat a sample and therefore would not have the quantity of concentrated urea around the sample to react with the urease, providing a less visible reaction. Additionally, the water added to the urea

In accordance with the claims and the teachings within the Rothgang specification, the reagent mixture is a combination of urea with at least a buffer to set the pH value. (Page 5, lines 19 – 20) In addition to the urea and a buffer, when the compressed mixture is used, the indicator can also be within the same product. (Page 7, lines 10 – 11; page 9, lines 17-20) Alternatively, the indicator can be contained in the water used to activate the reaction (Page 7, lines 12-13) or on the test surface, such as filter paper (Page 7, line 13; page 9, lines 21-25 – page 10 lines 1-2)

In all of the embodiments in the Rothgang patent, it consistently teaches the use of

water, or other liquid, and the inclusion of a buffer with the urea.

In the instant invention as covered in amended independent Claims 1 and 9, there are two distinct, physically separated, compositions. In the first container, or well, is a fine powdered urea and in the second container, or well, is the indicator, possibly combined with other materials such as agar, buffers, etc. In the embodiment of Claims 1-14 of the instant invention, the only addition to the urea that is taught is the use of a powdered anti-caking agent to maintain the urea in the non-compacted condition; a material that would be, at best, superfluous and at worst counterproductive, in the Rothgang teachings. Since Rothgang's preferred embodiment uses a compressed mixture, the addition of an anti-caking agent would be directly opposite to the patent's teachings.

As set forth in Claims 1 – 14 of the instant invention, the specimen is first placed into the finely powdered urea and then moved to the indicator, at which time the reaction starts, indicating either the presence or lack of presence of ammonia. Because the urea is in a finely powdered state the urea adheres to the sample. (Page 7, lines 13-16) There is neither the addition of water nor the exposure to both the urea and the indicator simultaneously taught in the embodiments of these claims.

In an alternate embodiment claimed in Claims 15 – 18 the urea and indicator have been combined, both in a finely powdered form, again for direct contact with the sample. The combination in accordance with the instant invention does not, however, contain a buffer substance, as set forth in Rothgang Claim 1, (b) nor does it require the addition of a liquid.

In Rothgang the three ingredients are a) urea, b) buffer substance and c) pH indicator, with the reagent mixture containing at least the urea and buffer. The pH indicator, in accordance with Rothgang's claim 1, is not necessarily a part of the mixture.

Although the Rothgang patent teaches the weight of the compressed product, it does not address the particle size of any of the ingredients. As the embodiments of Rothgang call for the addition of water to dissolve the powder or crushed components, particle size would be irrelevant.

Conversely, in the instant invention small particle size is advantageous. As stated on page 8, lines 8 – 11, the sample is contacted with the urea composition, causing the urea to stick to the sample. In the pending application, the moisture inherent in the sample causes the urea to adhere to the sample and provides any moisture required for the reagent activation. It is well known in the sciences that the smaller the particle size, the greater number of particles that

can adhere to a surface area. The specification specifically teaches at page 9 lines 10 – 19, that the smaller the particle size, the more particles adhere to the sample and the more efficient the test.

It is submitted that the differences between the Rothgang patent and the instant invention include, but are not limited to:

Marshall – pending claims

No water is added to the urea

No buffers are added to the urea

Dry indicators can be added to the urea

Rothgang

Added water is required to activate the urea /buffer combination

Buffers are required to be added to the urea in accordance with Claim 1

Indicators can be added to the urea or to the liquid used for activation

All ingredients are finely powered and not compacted within the respective testing area(s)	Urea/buffer combination can be compressed or put into capsules
Anti-caking material can be added to urea	Anti-caking would be unnecessary, or adverse, to the working of the invention
Finer urea particles increase efficiency	Particle size is not addressed

It is respectfully submitted that the currently pending amended claims clearly reflect the differences between the instant invention and the Rothgang method for determining the presence of urease.

Claims 1, 6-10 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by either of U.S. Patent 4,585,623 to Chandler or U.S. Patent 4,690,801 to Anderson.

Chandler teaches the use of a powdered urea in a device for performing chemical or immunochemical assays. As the Chandler patent is directed to the actual device, there is little teaching regarding urea other than it is maintained in a dry powdered state until an aqueous solution is introduced into the tube. Again, as in the Rothgang patent, a liquid is used to activate the process and the dry state is used to maintain purity until use.

Claims 6 and 16 of the pending application, relating to the particle size, are dependent claims and it is submitted that these claims are patentable as all claims either include, or are dependent upon, a novel patentable method for determining the presence of urease.

The Examiner states that as urea is known to be available in a powdered state that a particle size of “less than about 0.1 mm” is deemed as inherent in the Chandler disclosure. It is submitted that as the Chandler patent teaches the addition of liquid to the urea, the particle size is not particularly relevant.

Further, as none of the cited patents disclose a size range, it is requested that the Examiner provide a basis for the statement that the particle size of "less than about 0.1 mm" as being inherent in the prior art.

The Anderson patent is another apparatus used for performing quantitative or qualitative assays. The device contains several reservoirs, the third of which contains two compartments separated by a frangible seal. The urea is maintained in one of the compartments with a reagent liquid in the other compartment. When the frangible seal between the two compartments is broken, the urea and reagent liquid mix and, upon the rupturing of a second frangible seal, flow into and through the tubes.

Again, as in the Rothgang and Chandler patents, the urea is maintained in the dry state until mixed with a liquid immediately prior to use. As stated in the specification and in the foregoing remarks the pending application does not use water but rather relies on the inherent moisture within the sample to activate the reagents.

The Examiner has stated, in reference to both the Chandler and Anderson patents, that the film claimed in claim 14 could be interpreted as a thin sheet of any material. Applicant is not claiming the use of a covering to maintain a material within a receptacle, but rather as a dependent claim providing a feature limited to the scope of the independent claim. It is therefore submitted that this claim is patentable as this claim either includes, or is dependent upon, a novel patentable method for determining the presence of urease.

35 U.S.C. §103

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over either of Chandler or Anderson in view of Rothgang et al. The Examiner states that would have been obvious, in view of the foregoing patents, to use bromothymol blue or phenol red as indicators to show the presence of bacteria indicating ammonia.

It is respectfully submitted that applicant is not patenting bromothymol blue, phenol red or the use of indicators. Applicant is rather patenting a novel test procedure to indicate the presence of ammonia. As claim 12 is a dependent claim, it does not stand patentability wise on its own and obtains its patentability from the corresponding independent claim.

Applicant wishes to bring to the Examiner's attention a test called "Pronto Dry" which uses the water in the sample to create the reaction onto colored test paper. This product does not produce the reliable, long lasting results of the instant invention. In the Pronto Dry once the sample is in contact with the absorbent paper, the hydration evaporates, causing the color to

fade within a few hours. The speed of the process may provide some advantages, but also provides other disadvantages. In the instant invention, the use of a gel maintains the moisture within the sample creating a sample that is color stable for weeks.


Double Patenting

Applicant agrees to execute any required terminal disclaimers once a review of the technology recently transferred to him is completed. Some of the cases are being dropped and other cases being refiled with claims directed to other inventions within the case.

If the Examiner has any questions or concerns regarding the present response, the Examiner is invited to contact Sheldon Parker at 703-591-2664, Ext. 2041.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance, and favorable action is respectfully solicited.

Respectfully submitted,


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